DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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WARNING LETTER

OCT 25 1999

Mr. Daryl Mathias
Accutech Orthodontic Laboratory
4012 Raintree Road, Suite 120B
Chesapeake, Virginia 23321

Re: SAGA (Sleep Apnea Goldilocks Appliance)

Dear Mr. Mathias:

We are writing to you because on March 23, 1999, a letter was sent to you concerning your sale of the Sleep Apnea Goldilocks Appliance without having the necessary clerance from the FDA. As you were advised at that time, under United States Federal law (the Federal Food, Drug, and Cosmetic Act (the Act)), this product is considered to be a medical device.

Our records indicate that you have never responded to our March letter. Therefore, we have no indication that you have ceased distribution of the SAGA device and, to date, the agency has not received a premarket notification submission (510(k)) from you in an effort to obtain clearance from the agency.

Because you do not have marketing clearance from FDA, marketing your product is a violation of the law. In legal terms, the product is adulterated under section 501(f)(1)(B) and misbranded under section 502(o) of the Act. Your product is adulterated under the Act because you did not obtain premarket approval based on information developed by you that shows your device is safe and effective. Your product is misbranded under the Act because you did not submit information that shows your device is substantially equivalent to other devices that are legally marketed.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you receive this letter whether you are still marketing this device and what steps you are taking to correct the problem. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Sharon Kalokerinos, Dental, ENT and Ophthalmic Devices Branch, Division of Enforcement II, Office of Compliance, at the letterhead address.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of premarket clearance for your device and does not necessarily address other obligations (e.g., registration and listing) you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-800-638-2041 or through the Internet at www.fda.gov and select the Center for Devices and Radiological Health.

If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact the Dental, ENT and Ophthalmic Devices Branch within the Office of Compliance at (301) 594-4613.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health